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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,821	12/07/2001	Hyun-Soo Kim	3267/FLK/(032878-00052)	9666

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KATTEN MUCHIN ROSENMAN LLP
575 MADISON AVENUE
NEW YORK, NY 10022-2585

EXAMINER	
CHOI, FRANK I	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 10/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/016,821	KIM ET AL.	
	Examiner	Art Unit	
	Frank I. Choi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/536,163.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The amended claims recite "in amounts not preventing the tablet for disintegrating in the oral cavity within 60 seconds". The Specification does not appear to explicitly recite said limitation and the Applicant has not indicated their basis for reciting the same in the claims by specific citation to the disclosure or disclosures in the Specification that provides antecedent basis for the same. The Examiner respectfully requests that the Applicant indicate in the record the basis for said amendment by citing specifically to disclosure in the Specification which provides antecedent basis for said amendment, provide an explanation as to why the cited disclosure provides antecedent basis for said amendment and amendment of the Specification to include said limitation, provided that any such amendment does not add new matter to the Specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/78292 in view of Serpelloni et al. (US Pat. 5,573,777).

WO 00/79292 discloses that a quickly disintegrating solid preparation comprising an active ingredient, such as acetaminophen, scopolamine, famotidine or meclizine, D-mannitol with a mean particle diameter of 30 micrometers to 300 micrometers, crospovidone and a cellulose compound, such as crystalline cellulose, powder cellulose, low substituted hydroxypropyl cellulose and carmellose (Pg. 2, lines 22-24, Pg. 3, lines 10-19, Pg. 5, lines 3-29, Pgs. 6, 7, Pg. 8, lines 1-7;Column 2, lines 24-27, 56-68, Column 3, lines 1-5, Column 4, lines 21-68, Column 5, Column 6, lines 1-18). It is disclosed that the amount of the mannitol is 40 to 95 parts per 100 parts of the solid pharmaceutical preparation and that the amount of crospovidone is preferably 1 to 10 parts per 100 parts of the solid pharmaceutical preparation (Page 10, lines 17-23;Column 7, lines 52-59). It is disclosed that the solid preparation can contain foaming agents, such as sodium bicarbonate, sodium carbonate, sour agents including, citric, tartaric or malic acid, sweeteners, such as aspartame, saccharin, lubricants, such as magnesium stearate, and flavoring agents, in amounts generally used in the preparation of pharmaceutical preparations provided that they do not interfere with the effect of the invention (Page 11, lines 20-29, Page 12, lines 1-19; Column 8, lines 31-68). It is disclosed that the time required for intraoral disintegration is preferably about 5 to about 60 seconds and that the tablet hardness is preferably about 10 to 150 N, and, thus, can be used by patients, aged people and children who have difficulty swallowing medicine and is excellent in long-term storage and stability (Pg. 14, lines 1-21;Column 10, lines 8-43). The cites to column and line numbers refer to US Patent 6,740,339 which is the 371 of WO 00/79292.

Serpelloni et al. discloses mannitol which is prepared by atomizing an aqueous solution of mannitol and granulating the atomized powder where the mannitol has a mean diameter of

135 microns with approximately 86% of the particles having a size greater than 100 microns, moderate and not excessive friability, good ability to flow, a very high rate of solubilization of 26 seconds and forms tablets having a hardness of 78 N (Column 10, lines 1-49, Column 12, lines 40-63).

The prior art discloses a tablet that disintegrates within 60 seconds, containing mannitol, crospovidone, and one or more organic acids, foaming agents, sweeting agents, diluents, and flavoring agents. The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the use of spray-dried mannitol of which at least 80% has an average particle size over 100 micrometers in combination with crospovidone. However, the prior art amply suggests the same as the prior discloses the use of mannitol in combination with crospovidone in a tablet that disintegrates in less than 60 seconds and discloses a mannitol having properties which fall within the scope of the claimed mannitol. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the Serpelloni et al. mannitol would be suitable for use in the WO 00/78292 product and that the product would be suitable for persons who have difficulty in swallowing solid medications.

The Examiner has duly considered the Applicant's arguments but deems them unpersuasive.

The Applicant argues that the WO 00/782292 reference was published on December 28, 2000, which is later than the priority date of March 25, 1999. The Applicant indicates that the present Application of is a CIP of application no. 09/536,163, filed March 25, 2000, claiming priority to a Korean Patent Application, filed on March 25, 1999. However, the Applicant is not

entitled to the priority date of either the Korean Patent Application or the CIP. As a preliminary matter, the Applicant has not provided a certified translation of the Korean Patent Application in the present Application. Notwithstanding the same, even if one was provided, the claims contain subject matter that does not appear to have written description support pursuant to 35 USC 112, 1st paragraph, in the parent application. See Studiengesellschaft Kohle m.b.H. v. Shell Oil Co., 42USPQ2d 1674, 1677 (CAFC 1997) (a claim complies with 35 U.S.C. Section 120 and acquires an earlier filing date if, and only if, it could have been added to an earlier application without introducing new matter). The claims require spray-dried mannitol of which at least 80% has an average particle size over 100 microns. There does not appear to be any written description support in the '163 application for said limitation. As such, the claims are only entitled to the filing date of the present application, December 7, 2001, which is after the publication date indicated above.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Thursday, Friday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Dr. Johann Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi
Patent Examiner
Technology Center 1600
October 10, 2006

Johann Richter, Ph. D. Esq.
Supervisory Patent Examiner
Technology Center 1600